REMARKS

The Official Action dated July 15, 2003 has been carefully considered. Accordingly, the changes presented herewith, taken with the following remarks, are believed sufficient to place the present application in condition for allowance. Reconsideration is respectfully requested.

By the present Amendment, the specification has been amended to omit the "http:www." portion of the internet addresses and/or to capitalize each noted trademark. Claims 1, 4-7, 9 and 10 remain in the application. Claims 2-3 and 8 have been cancelled as a result of the Examiner's restriction requirement. In view of the Examiner's restriction requirement, Applicant retains the right to present claims 2-3 and 8 in a divisional application. Claim 1 has been amended to clarify the limitations therein, specifically to replace "comprising" with "consisting essentially of." It is believed that these changes do not involve any introduction of new matter, whereby entry is believed to be in order and is respectfully requested.

The disclosure was objected to because it contains embedded hyperlinks and/or other forms of browser executable code. The Examiner also noted the use of trademarks in the application and required that the specification be amended to capitalize each trademark as well as include generic terminology. In response to these objections, Applicant notes that it is not intended to have the hyperlinks recited in the specification as active links and therefore, the specification has been amended to omit the "http:www" portion of the internet addresses. In addition, the specification has been amended to capitalize each trademark recited in the application. Finally, Applicant submits that the specification discloses generic terminology for each cited trademark. It is therefore believed that the objections to the specification have been overcome. Reconsideration is respectfully requested.

Claim 3 was objected to for an informality. As claim 3 has been cancelled, the objection to claim 3 has been overcome.

Claims 1, 4-7, 9 and 10 were rejected under 35 U.S.C. §101 on the basis that the claimed invention is not supported by either a specific asserted utility or a well-established utility. These claims were also rejected under 35 U.S.C. §112, first paragraph, the Examiner asserting that since the claimed invention is not supported by either a specific asserted utility or a well established utility, one skilled in the art would not know how to use the claimed invention. Specifically, the Examiner asserted that the Applicant fails to describe how the claimed molecule would be useful regarding metabolic diseases and fails to describe how to use or administer the nucleic acid in such treatment, diagnosis or other actual use. In addition, the Examiner asserted that the Applicant states on page 8 of the specification that the protein encoded by the nucleic acid molecule has an "unknown function."

However, Applicant submits that the present specification establishes utility of the presently claimed invention in accordance with the requirements of 35 U.S.C. §101 and teaches one of ordinary skill in the art how to use the claimed invention in accordance with the requirements of 35 U.S.C. §112, first paragraph. Accordingly, these rejections are traversed and reconsideration is respectfully requested.

More particularly, claim 1 is directed to an isolated nucleic acid molecule selected from (a) nucleic acid molecules consisting essentially of a nucleotide sequence as shown in SEQ ID NO: 1 or 3; (b) nucleic acid molecules consisting essentially of a nucleotide sequence capable of hybridizing, under stringent hybridization conditions, to a nucleotide sequence complementary to the polypeptide coding region of a nucleic acid molecule as defined in (a); and (c) nucleic acid molecules consisting essentially of a nucleic acid sequence

which is degenerate as a result of the genetic code to a nucleotide sequence as defined in (a) or (b).

As set forth at page 1, the specification clearly discloses that the present invention relates to a group of polypeptides referred to as "Protein Cluster II", which are useful in the diagnosis of metabolic diseases, such as obesity and diabetes, as well as in the identification of agents useful in the treatment of such diseases. Accordingly, the specification has clearly set forth a specific and substantial utility for the claimed invention. Applicants also note that the use of the phrase "unknown function" at page 8 of the specification refers to the fact that this group of homologous proteins now known as "Protein Cluster II" previously had an unknown function. However, upon Applicant's discovery of the claimed invention, Protein Cluster II has now been identified as useful in the diagnosis of metabolic diseases as well as in the identification of agents useful in the treatment of such diseases.

As Applicant clearly discloses that the claimed nucleic acid molecules are useful in the diagnosis of metabolic diseases as well as in the identification of agents useful in the treatment of the such diseases, Applicant has disclosed a credible, specific and substantial utility for the claimed invention. Thus, the utility requirement of 35 U.S.C. §101 has been met. Moreover, as Applicant has disclosed a utility for the claimed invention, one of ordinary skill in the art would appreciate how to use the claimed invention without undue experimentation. That is, one of ordinary skill in the art is familiar with the general techniques of and can easily practice diagnosis of metabolic diseases and identification of agents useful in treatment of such diseases. Accordingly, the requirements of 35 U.S.C. §112, first paragraph, are met. It is therefore submitted that these rejections to the claims have been overcome. Reconsideration is respectfully requested.

Claim 1 was rejected under 35 U.S.C. §102(b) as being anticipated by Birren et al (AC009938; 08-Sep-1999, Whitehead Institute/MIT Center for Genome Research). The Examiner asserted that Birren et al teach a nucleic acid sequence with nearly 100% identity to SEQ ID NO: 1. The Examiner further noted that the language in claim 1 recites that "nucleic acid molecules comprising a nucleic type sequence as shown in SEQ ID NO: 1" includes smaller sequences that are found within SEQ ID NO: 1. Therefore, the Examiner asserted that Birren et al teach all of the elements of claim 1.

This rejection is traversed and reconsideration is respectfully requested. More particularly, as discussed in detail above, claim 1 is directed to an isolated nucleic acid molecule selected from: (a) nucleic acid molecules consisting essentially of a nucleotide sequence as shown in SEQ ID NO: 1 or 3; (b) nucleic acid molecules consisting essentially of a nucleotide sequence capable of hybridizing, under stringent hybridization conditions, to a nucleotide sequence complementary to the polypeptide coding region of a nucleic acid molecule as defined in (a); and (c) nucleic acid molecules consisting essentially of a nucleic acid sequence which is degenerate as a result of the genetic code to a nucleotide sequence as defined in (a) or (b).

Birren et al disclose a 156337 base pair sequence listing. However, Birren et al fail to teach or recognize an isolated nucleic acid molecules consisting essentially of a nucleotide sequence as shown in SEQ ID NO: 1 or 3, or the related nucleic acid molecules thereof defined in claim 1. Anticipation under 35 U.S.C. §102 requires the disclosure in a single prior art reference of each element of the claims under consideration, *Alco Standard Corp. v. TVA*, 1 U.S.P.Q.2d 1337, 1341 (Fed. Cir. 1986). While the nucleotide sequence of Birren et al may include a portion of the nucleic acid molecules identified as SEQ ID NO: 1, Applicant finds no teaching or reference by Birren et al of nucleic acid molecules consisting essentially

of a nucleotide sequence as shown in SEQ ID NO: 1 or 3, or the related nucleic acid molecules of claim 1. Rather, Birren et al provide a larger nucleotide sequence. Thus, Birren et al do not disclose each element of claim 1 and therefore do not support a rejection of this claim.

It is therefore submitted that Birren et al do not anticipate the nucleic acid molecule of claim 1, and that the rejection under 35 U.S.C. §102(b) has been overcome. Reconsideration is respectfully requested.

Claim 1, 4-7, 9 and 10 were rejected under 35 U.S.C. §103(a) as being unpatentable over Albertini et al, U.S. Patent No. 6,113,903, in view of Birren et al. The Examiner asserted that Albertini et al teach a method for treating metabolic disorder diabetes using vectors having an expression control sequence operatively linked to a nucleic acid molecule where it directs the transcription and translation in a host cell and making a polypeptide. The Examiner relied upon Birren et al as disclosing a nucleic acid sequence with nearly 100% identity to SEQ ID NO: 1. Therefore, the Examiner asserted that it would have obvious to one of ordinary skill in the art to use the nucleic acid molecule as taught by Birren et al to make a corresponding vector and host cell and to use the recombinant means to express the corresponding protein as taught by Albertini et al.

However, as will be set forth in detail below, Applicant submits that the nucleic acid molecule defined by claim 1, the vectors defined by claims 4 and 5, the cultured host cells defined by claims 6 and 9, and the processes defined by claims 7 and 10 are nonobvious over and patentably distinguishable from the cited combination of references. Accordingly, this rejection is traversed and reconsideration is respectfully requested.

More particularly, as defined in detail above, claim 1 is directed to an isolated nucleic acid molecule selected from: (a) nucleic acid molecules consisting essentially of a nucleotide

sequence as shown in SEQ ID NO: 1 or 3; (b) nucleic acid molecules consisting essentially of a nucleotide sequence capable of hybridizing, under stringent hybridization conditions, to a nucleotide sequence complementary to the polypeptide coding region of a nucleic acid molecule as defined in (a); and (c) nucleic acid molecules consisting essentially of a nucleic acid sequence which is degenerate as a result of the genetic code to a nucleotide sequence as defined in (a) or (b). Claims 4-7, 9 and 10 employ all isolated nucleic acid sequence according to claim 1.

Albertini et al disclose peptides and methods against diabetes. However, Applicant finds no teaching, suggestion or reference of a nucleic acid molecule consisting essentially of a nucleic acid sequence as shown in SEQ ID NO: 1 or 3, or the related nucleic acid molecules defined in claim 1. Similarly, Applicant finds no teaching, suggestion or reference by Albertini et al of vectors, cultured host cells or processes employing such. The deficiencies of Albertini et al are not resolved by Birren et al. That is, as discussed in detail above, Birren et al fail to teach, suggest or recognize an isolated nucleic acid molecule consisting essentially of a nucleic acid sequence as shown in SEQ ID NO: 1 or 3, or the related nucleic acid molecules defined in claim 1. References relied upon to support a rejection in 35 U.S.C. §103 must provide an enabling disclosure, i.e. they must place the claimed invention in the possession of the public, *In re Payne*, 203 USPQ 245 (CCPA 1979). In view of the failure of Albertini et al and Birren et al to teach, suggest or recognize an isolated nucleic acid molecule as defined by claims 1, 4-7, 9 and 10, the cited combination of these references cannot and do not provide an enabling disclosure of the present invention and therefore does not support a rejection of the claims under 35 U.S.C. §103.

In addition, as Birren et al merely disclose an unidentified sequence listing, Applicant finds no teaching, suggestion or reference that suggests its combination with Albertini et al.

"Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion, or incentive supporting the combination," *In re Geiger*, 2 USPQ2d 1276, 1278 (CAFC 1987). Not only does the combination of Albertini et al and Birren et al not result in the claimed invention, there is no motivation to combine the references. Accordingly, the present invention is nonobvious over and patentably distinct from the cited combination of references.

It is therefore submitted that the isolated nucleic acid molecules, vectors, cultured host cells and processes defined by the claims are not rendered obvious over Albertini et al in view of Birren et al and are patentably distinguishable therefrom, whereby the rejection under 35 U.S.C. §103 has been overcome. Reconsideration is respectfully requested.

It is believed that the above represents a complete response to the objections and rejections under 35 U.S.C. §§101, 102, 103 and 112, first paragraph, and places the present application in condition for allowance. Reconsideration is requested.

Respectfully submitted,

By _____

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